510(k) SUMMARY

K101918

SEP 24 2010

Submitted By:

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Submission Contact: Jennifer Hankard

Date Prepared: July 8, 2010

Device Trade Name: QuickVue® RSV 10

Common Name: Respiratory Syncytial Virus (RSV) Test

Predicate Device: QuickVue RSV test (K061008 and K070747)

Device Classification/Name: 21 CFR 866.3480 / Respiratory syncytial virus serological reagents

These tests are used to aid in the diagnosis of disease caused by respiratory syncytial viruses and provides epidemiological information on these diseases (21 CFR 866.3480). The Food and Drug Administration has classified serological test systems for the detection of respiratory syncytial virus as Class I.

Intended Use: The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.

Physiologic Basis of the Test:

Respiratory syncytial virus (RSV) is a single stranded (negative strand) RNA virus of the Paramyxoviridae family. It is the causative agent of a highly contagious, acute, viral infection of the respiratory tract in pediatric populations. Nearly half of all children become infected by their first year of life. It is also the major viral cause of nosocomial illness in children already hospitalized for other reasons. In the United States, RSV is estimated to be responsible for 73,400 to 126,300 hospitalizations annually for bronchiolitis and pneumonia alone among children younger than 1 year. In children hospitalized with RSV infection, it is believed to be the most common viral cause of death in children younger than 5 years, particularly in children younger than one year. Among children hospitalized with RSV infection, the mortality rate is estimated to be as low as 0.3% to 1.0% of hospitalized children and in the range of 2.5% to 4.0% for hospitalized children with underlying cardiac or pulmonary disease.

Device Description:

The QuickVue RSV 10 test is a lateral-flow immunoassay that uses monoclonal antibodies that are specific for RSV antigens. The test is specific to RSV antigen with no known cross-reactivity to normal flora or other known respiratory pathogens.

Nasopharyngeal swabs and nasopharyngeal aspirate/wash serve as specimens for this test. For a liquid specimen such as a nasopharyngeal aspirate/wash, the specimen is added directly to the reagent tube and rehydrates the reagent. When a nasopharyngeal swab is used, the reagent is first rehydrated with the provided reagent solution and the swab specimen is then inserted into the reagent tube.

The reagent interacts with the specimen and facilitates exposure of the appropriate viral antigens to the antibodies used in the test. The test strip is placed in the reagent tube for 10 minutes. During this time, the specimen will react with the reagents in the test strip.

If the specimen contains RSV antigens, a pink-to-red Test Line, along with a blue procedural Control Line will appear on the Test Strip indicating a positive result. If RSV antigen is not present, or is present at very low levels, only a blue procedural Control Line will appear.

Device Comparison:

Features	QuickVue RSV 10 test (Proposed)	QuickVue RSV test (K061008 and K070747)
Intended Use	The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.	The QuickVue RSV test is a dipstick immunoassay, which allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen (viral fusion protein) directly from nasopharyngeal swab, nasopharyngeal aspirate, nasal/nasopharyngeal wash specimens for symptomatic pediatric patients (eighteen years of age and younger). The test is intended for use as an aid in the diagnosis of acute respiratory syncytial viral infections. It is recommended that negative test results be confirmed by cell culture. Negative results do not preclude RSV infection and it is recommended that they not be used as the sole basis for treatment or other management decisions. The test is intended for professional and laboratory use.
Specimen Types	Nasopharyngeal swab, Nasopharyngeal aspirate/wash	Nasopharyngeal swab, Nasopharyngeal aspirate/wash Nasal wash
Reagent	Lyophilized buffer containing detergents	Liquid buffer solution containing detergents
Read Result Time	10 Minutes	15 Minutes
Format	Lateral-flow immunoassay dipstick	Lateral-flow immunoassay dipstick
Control Features	Procedural Control Line Clearing of background	Procedural Control Line Clearing of background
External Controls	Positive RSV swab RSV negative swab coated with Streptococcus C antigen	Positive RSV swab RSV negative swab coated with Streptococcus C antigen

Summary of Performance Data:

Numerous studies were undertaken to document the performance characteristics and the substantial equivalence of the test to the predicate device. These studies included the following:

1. A multi-center field clinical study was undertaken to document the performance characteristics of the test. Sensitivity and specificity were calculated using nasopharyngeal swabs and nasopharyngeal aspirate/wash specimens compared to viral culture.
2. A reproducibility study was performed to demonstrate intra- and inter-operator reproducibility and intra- and inter-laboratory reproducibility with a panel of test samples at various RSV concentrations.
3. Analytical studies demonstrated specimen transport and stability, intra- and inter-lot consistency, analytical sensitivity, limit of detection, kit stability, cross reactivity, analytical specificity, lack of interference with various substances, and test robustness with variations in the test method.

Conclusion:

These studies demonstrated the substantial equivalence of the QuickVue RSV 10 test to existing products already marketed.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Quidel Corporation
c/o Jennifer S. Hankard
Director, Regulatory Affairs and Quality Assurance
10165 McKellar Court
San Diego, CA 92121

SEP 24 2010

Re: K101918

Trade/Device Name:	QuickVue®RSV 10
Regulation Number:	21 CFR §866.3480
Regulation Name:	Respiratory syncytial virus serological reagents
Regulatory Class:	Class I
Product Code:	GQG
Dated:	July 8, 2010
Received:	July 9, 2010

Dear Ms. Hankard,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Uwe Scherf for

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

SEP 2 4 2010

510(k) Number (if known): k101918

Device Name: QuickVue RSV 10

Indications For Use:

The QuickVue RSV 10 test is an immunoassay that allows for the rapid, qualitative detection of respiratory syncytial virus (RSV) antigen directly from nasopharyngeal swab and nasopharyngeal aspirate/wash specimens for symptomatic pediatric patients (less than six years old). The test is intended for use as an aid in the rapid diagnosis of acute RSV infection. Negative results do not preclude RSV infection and should not be used as the sole basis for treatment or for other management decisions. A negative test is presumptive. It is recommended that negative test results be confirmed by cell culture. The test is intended for professional and laboratory use.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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